

(19)



Europäisches Patentamt  
European Patent Office  
Office européen des brevets



(11)

**EP 0 885 025 B1**

(12)

**EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention  
of the grant of the patent:  
**26.11.2003 Bulletin 2003/48**

(51) Int Cl.<sup>7</sup>: **A61M 1/28, A61J 1/00**

(86) International application number:  
**PCT/US97/16777**

(21) Application number: **97942635.0**

(87) International publication number:  
**WO 98/013079 (02.04.1998 Gazette 1998/13)**

(22) Date of filing: **22.09.1997**

**(54) SYSTEM FOR HOLDING AND DELIVERING A SOLUTION**

**SYSTEM ZUM AUFBEWAHREN UND ABGEBEN EINER LÖSUNG**

**SYSTEME PERMETTANT DE CONTENIR ET DE DISTRIBUER UNE SOLUTION**

(84) Designated Contracting States:  
**DE ES FR GB NL SE**

• **BELLOTTI, Marc**  
**Libertyville, IL 60048 (US)**

(30) Priority: **27.09.1996 US 722537**

(74) Representative: **MacGregor, Gordon**  
**Eric Potter Clarkson,**  
**Park View House,**  
**58 The Ropewalk**  
**Nottingham NG1 5DD (GB)**

(43) Date of publication of application:  
**23.12.1998 Bulletin 1998/52**

(73) Proprietor: **BAXTER INTERNATIONAL INC.**  
**Deerfield, Illinois 60015 (US)**

(56) References cited:  
**WO-A-83/02061**                      **WO-A-96/39207**

(72) Inventors:

• **LO, Ying-Cheng**  
**Green Oaks, IL 60048 (US)**

**BEST AVAILABLE COPY**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

**EP 0 885 025 B1**

## Description

### BACKGROUND OF THE INVENTION

[0001] The present invention generally relates to a system for holding and dispensing a solution. More specifically, the present invention relates to a system for delivering a solution to a patient undergoing peritoneal dialysis as well as draining a peritoneum of the patient.

[0002] It is, of course, known to administer solutions to patients. One such procedure that requires delivery of a solution to a patient is for a patient undergoing peritoneal dialysis.

[0003] In a known procedure for continuous ambulatory peritoneal dialysis (CAPD), two containers are required to perform the procedure. A first container, or drain bag, is provided along with a length of tubing that is connectable to the peritoneum of a patient for draining the peritoneum. A second container, or solution container, includes a dialysate therein for feeding to a patient. After the peritoneum fluid is drained into the drain bag, the solution bag is connected to the patient. The dialysate is delivered via the tubing from the solution bag to the peritoneum of the patient.

[0004] The use of two bags to perform CAPD, however, requires a number of additional steps. For example, prior to delivering the dialysate to the patient, the tubing connected to the solution bag must be primed in order to remove any air from the tubing. In addition, frangibles are often provided or required in the lengths of the tubing or connectors connected to the tubing. Selective fluid communication is initiated by breaking of the frangible thereby allowing dialysate to flow from the solution bag into the peritoneum of the patient.

[0005] WO-A-83/02061 describes a solution bag formed of three plastic walls sealed together about their peripheries to define a pair of separate chambers.

[0006] As is clearly evident from the foregoing, the known procedure is complex in that a number of components and additional steps are often required to perform the procedure. More specifically, at least a solution bag, a drain bag, tubing extending from each of the bags, connectors, at least one frangible, and caps on the connectors are required to perform CAPD using a two bag system.

[0007] A need, therefore, exists for an improved system, method and container that overcomes the deficiencies of known systems and procedures for administering solutions and simplifies the known procedures and systems.

### SUMMARY OF THE INVENTION

[0008] According to the present invention, there is provided a system for holding and administering a solution according to claim 1. The system comprises a container that holds the solution for delivery, for example, to a patient undergoing peritoneal dialysis, and also is

capable of receiving solution separately from the area in which the solution is held.

[0009] In an embodiment of the present invention, a system is provided for holding and administering a solution. The system has a container having walls defining an interior holding the solution therein wherein the container is divided into two chambers in fluid communication therewith and further wherein the two chambers are substantially parallel to each other and are of substantially equal length. A separation line is formed between the two chambers along substantially the length of each of the two chambers.

[0010] In an embodiment, a port is provided which is in fluid communication with the two chambers.

[0011] In an embodiment, an aperture is provided at one end of one of the two chambers to suspend the chamber.

[0012] In an embodiment, the lengths of the two chambers are substantially greater than the widths.

[0013] In an embodiment, a medication port is provided in fluid communication with the two chambers.

[0014] In an embodiment, volume of one of the two chambers is greater than volume of the other one of the two chambers.

[0015] In an embodiment, volume of one of the two chambers is at least 1.5 times greater than volume of the other one of the two chambers.

[0016] In an embodiment, the solution may be delivered to the patient without additional tubing.

[0017] A method of delivering a solution to a patient may comprise the steps of: providing a container having an interior holding a solution wherein the container is divisible into two chambers; providing a port in fluid communication with each of the two chambers; sealing a portion of the container to separate the solution into only one of the two chambers; and connecting the port to the patient to provide fluid communication with the patient.

[0018] The method may further comprise the step of connecting a length of tubing between the port and the patient.

[0019] In an embodiment, a medication port is provided in fluid communication with the two chambers.

[0020] The method also may further comprise the step of suspending one of the two chambers through an aperture at one end of the chamber.

[0021] The method may further comprise the step of separating the two chambers along a length of the two chambers such that one chamber is substantially sealed from the other chamber.

[0022] The method may further comprise the step of separating the two chambers along a line of separation extending substantially along a length between the two chambers wherein the line of separation may be selectively broken to separate the two chambers along the line of separation.

[0023] In an embodiment, one of the two chambers has a volume greater than the other one of the two chambers.

[0024] In an embodiment, the tear line is selectively separable to divide the first chamber from the second chamber and maintain fluid communication between the first chamber and the second chamber.

[0025] It is, therefore, an advantage of the present invention to provide a system for simplifying administration of a solution to a patient.

[0026] Another advantage of the present invention is to provide a system for administering a solution to a patient that is simple to manufacture.

[0027] Yet another advantage of the present invention is to provide a system that may be used as both the solution bag and the drain bag.

[0028] And, another advantage of the present invention is to provide a system that administers solution to a patient without requiring additional tubing.

[0029] Moreover, an advantage of the present invention is to provide a system that is easily separable between two separate chambers prior to use.

[0030] A still further advantage of the present invention is to provide a system that administers solution to a patient without priming of tubing.

[0031] Yet another advantage of the present invention is to provide a system in which sticking of film materials is eliminated during sterilization.

[0032] And, another advantage of the present invention is to provide a system that requires shorter sterilization times with more uniform temperature distribution in the bag.

[0033] These and other advantages of the present invention are described in, and will be apparent from, the detailed description of the presently preferred embodiments and from the drawings.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

[0034]

Figure 1 illustrates a plan view of an embodiment of a system of the present invention for holding and administering a solution.

Figure 2 illustrates a plan view of an embodiment of the system of the present invention illustrated in Figure 1 during a draining phase.

Figure 3 illustrates a plan view of an embodiment of the system of the present invention illustrated in Figure 1 during a stage in which solution is administered to a patient from a container.

Figure 4 illustrates a plan view of an alternate embodiment of a system of the present invention for holding and administering a solution to a patient.

Figure 5 illustrates a plan view of yet another embodiment of a system of the present invention for holding and administering a solution to a patient.

#### **DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS**

[0035] The present invention provides a system for holding and delivering a solution. The container used in the system of the present invention is multi-chambered having interiors holding a solution. The solution may be manipulated from one chamber to another during use of the system to perform the method of the present invention.

[0036] Referring now to the drawings wherein like numerals refer to like parts, Figure 1 illustrates a system 1 including a container 10 having a solution 12 within an interior 14 of the container 10. The container 10 is divided into a solution side 16 and a drain side 18 separated by a tear line 20. The solution side 16 and the drain side 18 are in fluid communication at an end 22 of the container 10 through a channel 23 such that the solution 12 within the container 10 may be isolated on either the solution side 16 or the drain side 18. At an opposite end 24 of the container 10 on the solution side 16 is an aperture 26 whose function will be described with reference to Figures 2 and 3.

[0037] In fluid communication with the container 10 is a port 28. Also provided is an optional medication port 30 used to provide medication to the interior 14 of the container 10, if necessary. In operation, the port 28 may be connected to a length of tubing 32. Alternatively, the port 28 may be connected directly to a device connected to a patient that provides fluid communication with, for example, a peritoneum cavity of the patient.

[0038] As illustrated, the drain side 18 of the container 10 is larger in volume than the solution side 16. In a preferred embodiment, the drain side 18 has a volume at least 1.5 times greater than the solution side 16. The walls of both the solution side 16 and the drain side 18 are preferably tapered as illustrated in Figure 1. The channel 23 formed at the end 22 of the container 10 allows the solution 12 to freely flow from either the solution side 16 or the drain side 18 of the container 10. The channel 23 is formed between a terminating end 34 of the tear line 20 and the end 22 of the container 10. During manufacture of the container 10, the tear line 20 is formed by a sealing technique well-known by those skilled in the art. The tear line 20 is formed substantially simultaneously with the formation of the walls of the container 10.

[0039] Referring now to Figures 2 and 3, use of the container 10 by a patient 35 is illustrated. To begin operation, the solution 12 within the container 10 is first transferred to the solution side 16 of the container 10. Therefore, prior to draining of the peritoneum cavity of the patient 35, the drain side 18 is substantially empty through isolation of the solution 12 on the solution side 16 of the container 10. After transferring the solution 12 to the solution side 16, a clamp 36 is placed at a point to separate the port 28 from the solution 12. Either prior to clamping or prior to draining of the peritoneum of the

patient 35, the tear line 20 is torn to separate the solution side 16 from the drain side 18. The solution side 16 may be suspended by a hook (38) or other known means through the aperture 26 at the end of the drain side 18 of the container 10 as illustrated. The peritoneum of the patient 35 is then drained into the drain side 18 of the container 10.

[0040] After draining the peritoneum or substantially after completion of the same, the clamp 36 may be moved to the position illustrated in Figure 3. Preferably, a second clamp is placed in the position illustrated in Figure 3 and then the clamp 36 illustrated in the position in Figure 2 is removed from the solution side 16. At this stage, the drain side 18 is at least partially filled with drainage from the peritoneum cavity of the patient 35 as generally designated by 40 in Figures 2 and 3.

[0041] Then, the solution 12 in the solution side 16 of the container 10 may be drained through the port 28 into the peritoneum cavity of the patient 35. A tubing 32 is illustrated connected between the port 28 and the peritoneum cavity of the patient 35. However, the port 28 may be directly connected to a connecting device (not shown) that, in turn, is connected to the peritoneum cavity. After the solution 12 is drained from the solution side 16 into the peritoneum cavity of the patient 35, the container 10 may be disconnected from the patient 35.

[0042] Referring now to Figures 4 and 5, alternate embodiments of the system illustrated in Figure 1 are illustrated. As shown in Figure 4, a system 100 includes a container 110 having a solution 112 located within the interior 114 of the container 110. This tube can be obtained from blown film process. The interior of the container 110 is divided into a solution side 116 and a drain side 118. A clamp or clamps (not shown) may be placed across a width of the container 110 in positions that maintain the solution 112 on the solution side 116 during draining of the peritoneum cavity into the drain side 118 through a port 120. After draining, a second clamp may be placed across a width of the container 110 to maintain the drainage from the peritoneum cavity on the drain side 118. Then, the first clamp may be removed to allow draining of the solution 112 from the solution side 116 into the peritoneum cavity. Although not shown, the container 110 may include an aperture on the solution side 116 such that the system 100 may be suspended similar to the manner illustrated in Figures 2 and 3.

[0043] Referring now to Figure 5, another alternate embodiment of a system 200 is illustrated with a container 210 having a solution 212 within an interior 214 of the container 210. Again, the container 210 includes a solution side 216 and a drain side 218. The solution side 216 and the drain side 218 are divided by a tear line 220. To use the system 200, the solution side 216 and the drain side 218 are separated at the tear line 220. A clamp (not shown) may be placed at a point across a width of the solution side 216 to maintain or isolate the solution 212 on the solution side 216 and to prevent fluid communication of the solution 212 through a port 222.

A peritoneum cavity of a patient may then be drained through the port 222 into the drain side 218 of the container 210. A second clamp may then be placed at a point across a width of the drain side 218 to prevent fluid communication of the drainage from the patient between the drain side 218 and the port 222. The first clamp may then be removed, and the solution side 216 may be drained of the solution 212 from the solution side 216 of the container 210 into the peritoneum cavity of the patient.

[0044] Although the present invention has been described with reference to a system and a method for use in peritoneal dialysis, it should be understood that the present invention may be implemented in other processes, such as, but not limited to, intravenous feeding. In addition, although the present invention, as illustrated, shows containers may from a flexible material, such as polyvinyl chloride (PVC), other materials may be implemented by those skilled in the art, such as non-PVC materials.

#### Claims

1. A system (1) for holding and administering a solution (12), the system comprising:

a container (10) having walls defining an interior (14) holding the solution therein wherein the container is divided into two chambers (16, 18) in fluid communication with each other and further wherein the two chambers are substantially parallel to each other and are of substantially equal length defined between a first end (24) and a second end (22) of the container, a port (28) in fluid communication with the two chambers and provided near to the second end (22) of the container,

characterised in that the system further comprises a tear line (20) formed between the two chambers along substantially a length of each of the two chambers wherein the tear line begins at the first end (24) and extends toward the second end (22) and the chambers are selectively separable along the tear line

2. The system of Claim 1 further comprising:

an aperture (26) at one end (24) of one of the two chambers (16) to suspend the chamber.

3. The system of Claim 1 wherein the lengths of the two chambers (16, 18) are substantially greater than the widths.

4. The system of Claim 1 further comprising:

a medication port (30) in fluid communication with the two chambers (16, 18).

5. The system of Claim 1 wherein the volume of one of the two chambers (18) is greater than the volume of the other of the two chambers (16).
6. The system of Claim 1 wherein the volume of one of the two chambers (18) is at least 1.5 times greater than the volume of the other of the two chambers (16).
7. The system of Claim 1 wherein the system is operable to deliver the solution (12) to a patient (35) without additional tubing.
8. The system of Claim 1, wherein the port (28) is connectable to a length of tubing (32).
9. The system of Claim 1, wherein a portion (23) of the container (10) is sealable so as to separate the solution (12) into only one of the two chambers (16, 18).
10. The system of Claim 1, wherein the chambers are separable such that one chamber is substantially sealed from the other chamber.
11. The system of Claim 1, wherein the chambers (16, 18) are selectively separable along the tear line (20) to divide the chambers and to maintain fluid communication between the chambers.

#### Patentansprüche

1. System (1) zur Aufbewahrung und Verabreichung einer Lösung (12), wobei das System folgendes aufweist:
  - einen Behälter (10), der Wände hat, die einen Innenraum (14) bilden, in dem die Lösung aufbewahrt ist, wobei der Behälter in zwei Kammern (16, 18) unterteilt ist, die miteinander in Fluidverbindung stehen, und wobei weiterhin die beiden Kammern im wesentlichen parallel zueinander sind und im wesentlichen die gleiche Länge aufweisen, die zwischen einem ersten Ende (24) und einem zweiten Ende (22) des Behälters definiert ist und
  - einen Anschluß (28) in Fluidverbindung mit den beiden Kammern, der in der Nähe des zweiten Endes (22) des Behälters vorgesehen ist,

dadurch gekennzeichnet,

daß das System zusätzlich eine Reißlinie (20) aufweist, die zwischen den beiden Kammern längs und im wesentlichen über eine Länge von jeder der bei-

den Kammern gebildet ist, wobei die Reißlinie an dem ersten Ende (24) beginnt und sich zu dem zweiten Ende (22) erstreckt und die Kammern gezielt entlang der Reißlinie trennbar sind.

2. System nach Anspruch 2, wobei das System zusätzlich eine Öffnung (26) an dem einen Ende (24) von einer der beiden Kammern (16) aufweist, um die Kammer aufzuhängen.
3. System nach Anspruch 1, wobei die Längen der beiden Kammern (16, 18) wesentlich größer als die Breiten sind.
4. System nach Anspruch 1, das zusätzlich einen Medikamentenanschluß (30) in Fluidverbindung mit den beiden Kammern (16, 18) aufweist.
5. System nach Anspruch 1, wobei das Volumen der einen der beiden Kammern (18) größer ist als das Volumen der anderen der beiden Kammern (16).
6. System nach Anspruch 1, wobei das Volumen der einen der beiden Kammern (18) zumindest 1,5-mal größer ist als das Volumen der anderen der beiden Kammern (16).
7. System nach Anspruch 1, wobei das System verwendet werden kann, um die Lösung (12) einem Patienten ohne zusätzliche Schläuche zuzuführen.
8. System nach Anspruch 1, wobei der Anschluß (28) an ein Schlauchstück (32) anschließbar ist.
9. System nach Anspruch 1, wobei ein Bereich (23) des Behälters (10) abdichtbar ist, um die Lösung (12) nur in eine der beiden Kammern (16, 18) zu separieren.
10. System nach Anspruch 1, wobei die Kammern trennbar sind, so daß die eine Kammer im wesentlichen gegenüber der anderen Kammer abgedichtet ist.
11. System nach Anspruch 1, wobei die Kammern (16, 18) gezielt entlang der Reißlinie (20) trennbar sind, um die Kammern zu trennen und dabei die Fluidverbindung zwischen den Kammern aufrechtzuerhalten.

#### Revendications

1. Système (1) pour contenir et administrer une solu-

tion (12), le système comprenant :

un récipient (10) ayant des parois qui définissent un intérieur (14) contenant la solution, dans lequel le récipient est divisé en deux chambres (16, 18) en communication mutuelle de fluide, et en outre dans lequel les deux chambres sont sensiblement parallèles l'une à l'autre et sont sensiblement de même longueur définie entre une première extrémité (24) et une deuxième extrémité (22) du récipient, une tubulure (28) en communication de fluide avec les deux chambres et prévue près de la deuxième extrémité (22) du récipient;

caractérisé en ce que le système comprend en outre :

une ligne de déchirure (20) formée entre les deux chambres sensiblement suivant une longueur de chacune des deux chambres, de sorte que la ligne de déchirure commence à la première extrémité (24) et s'étend vers la deuxième extrémité (22) et les chambres sont sélectivement séparables le long de la ligne de déchirure.

2. Système selon la revendication 1, comprenant en outre :

un trou (26) à une extrémité (24) d'une des deux chambres (16) pour suspendre la chambre.

3. Système selon la revendication 1, dans lequel les longueurs des deux chambres (16, 18) sont sensiblement plus grandes que les largeurs.

4. Système selon la revendication 1, comprenant en outre :

une tubulure de médicament (30) en communication de fluide avec les deux chambres (16, 18).

5. Système selon la revendication 1, dans lequel le volume d'une des deux chambres (18) est plus grand que le volume de l'autre des deux chambres (16).

6. Système selon la revendication 1, dans lequel le volume d'une des deux chambres (18) est au moins 1,5 fois plus grand que le volume de l'autre des deux chambres (16).

7. Système selon la revendication 1, dans lequel le système peut fonctionner pour administrer la solution (12) à un patient (35) sans tube additionnel.

8. Système selon la revendication 1, dans lequel la tubulure (28) est connectable à une longueur de tube (32).

9. Système selon la revendication 1, dans lequel une partie (23) du récipient (10) est fermable de façon à séparer la solution (12) dans une seule des deux chambres (16, 18).

10. Système selon la revendication 1, dans lequel les chambres sont séparables de sorte qu'une chambre est substantiellement isolée de l'autre chambre.

11. Système selon la revendication 1, dans lequel les chambres (16, 18) sont sélectivement séparables le long de la ligne de déchirure (20) pour diviser les chambres et maintenir une communication de fluide entre les chambres.

FIG.1

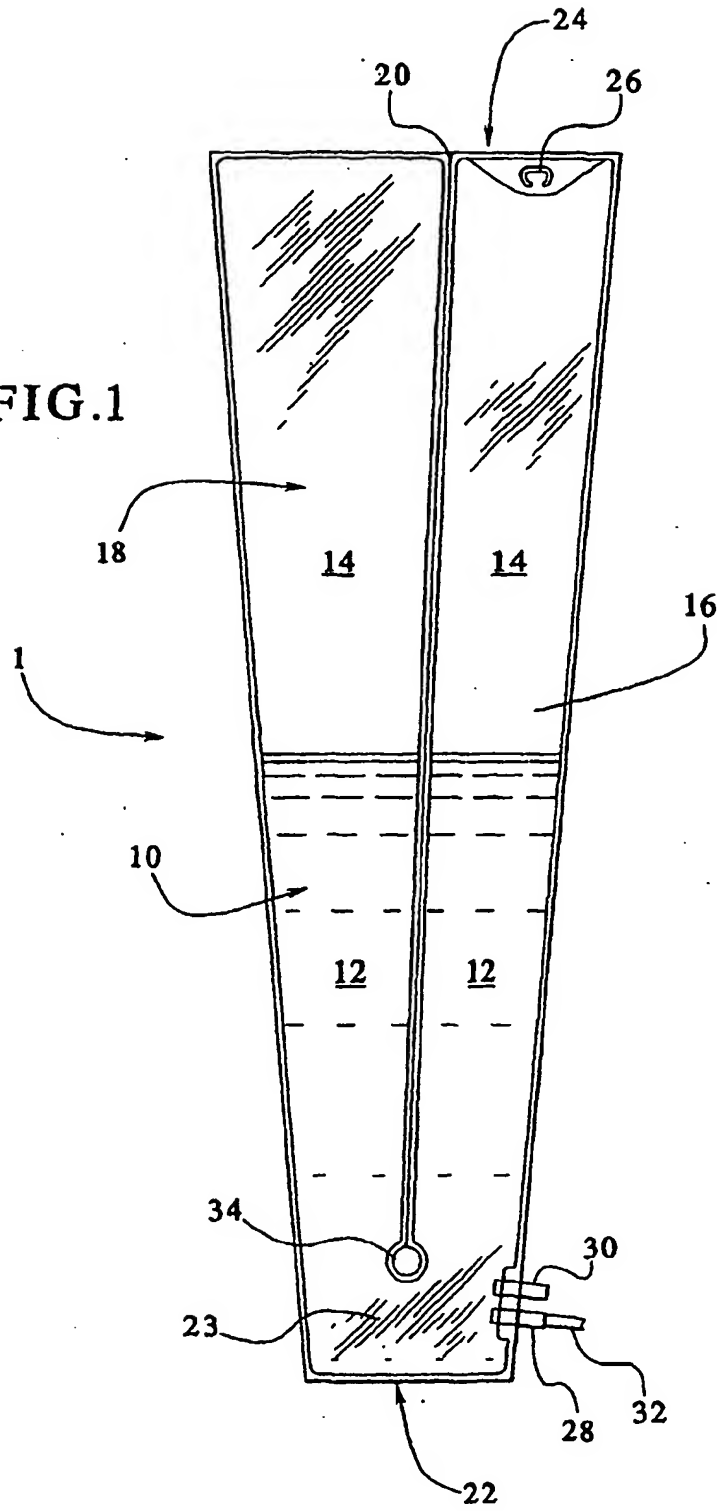


FIG.2

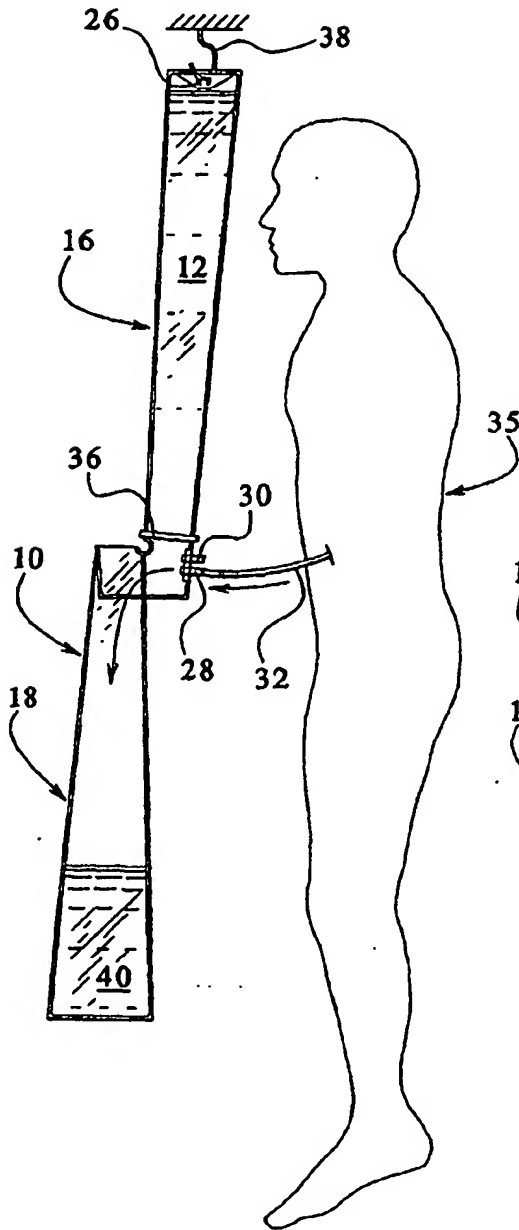


FIG.3

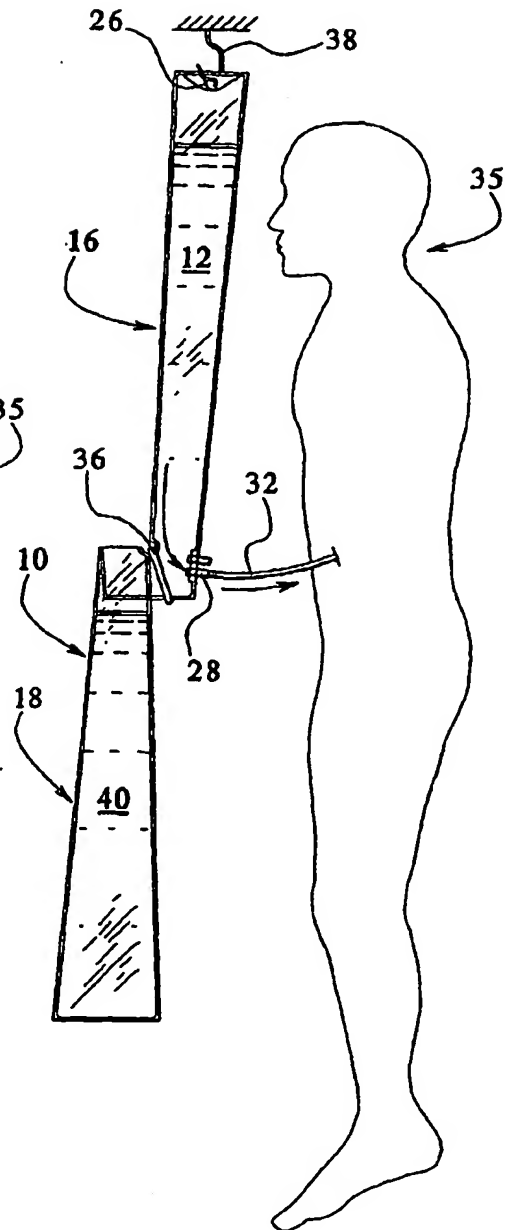




FIG. 4

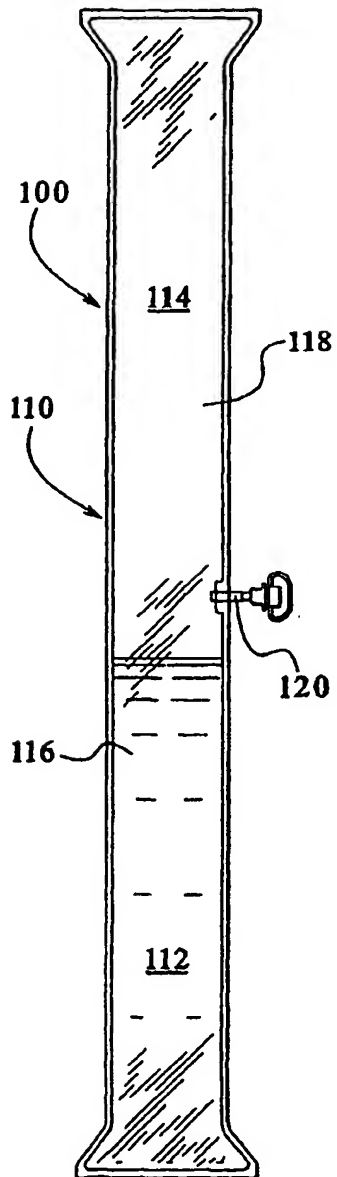
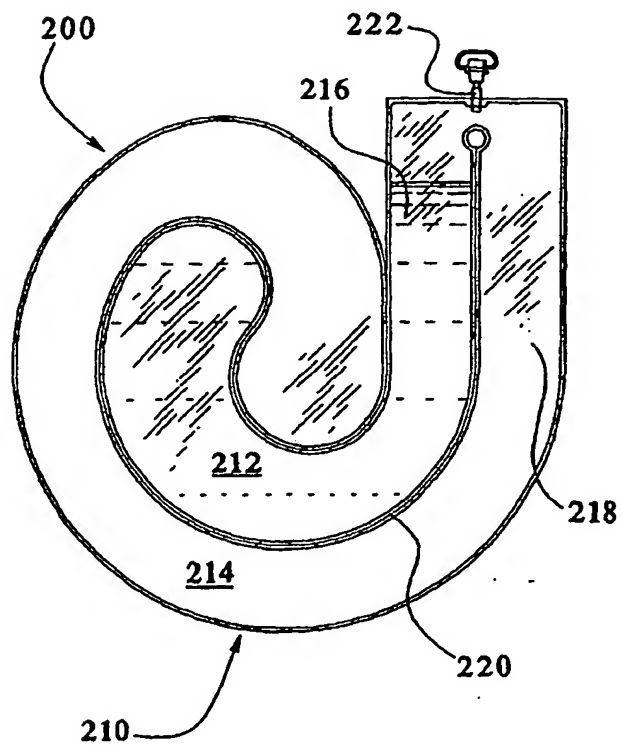


FIG. 5



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**